REMARKS

Claims 1-6, 10-34, and 95 are pending. Claim 1 has been amended. Claims 7-9 and 75-94 were previously canceled without prejudice or disclaimer. Claims 35-74 were previously withdrawn. No new matter has been introduced. Reexamination and reconsideration of the present application are respectfully requested.

In the May 13, 2009 Office Action, the Examiner rejected claims 1-6, 10-34, and 95 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent App. Pub. No. 2003/0060765 to Campbell et al. (the Campbell reference), in view of U.S. Patent No. 6,544,212 to Galley et al. (the Galley reference), and further in view of U.S. Patent App. Pub. No. 2003/0211617 to Jones (the Jones reference). The Examiner rejected claims 1-6, 10-34, and 95 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent App. Pub. No. 2003/0114836 to Estes et al. (the Estes reference), in view of the Galley reference, and further in view of the Jones reference. These rejections are respectfully traversed.

The present invention generally relates to apparatuses and methods for providing blood glucose measurements to an infusion device. Independent claim 1 has been amended to more accurately define the present invention.

Independent claim 1, as amended, recites:

> a characteristic determining device including:
>
> a determining device housing adapted to be carried by the user;

a receptacle coupled to the determining device housing for receiving and testing an analyte from the user to determine a concentration of the analyte in the user;

a determining device processor contained in the determining device housing and coupled to the receptacle for processing the determined concentration of the analyte from the receptacle; and

a determining device communication system contained in the determining device housing and coupled to the determining device processor for transmitting a communication including data indicative of the determined concentration of the analyte in the user; and

an infusion device including:

an infusion device housing adapted to be carried by the user;

a drive mechanism contained in the infusion device housing and operatively coupled with a reservoir containing the fluid for infusing the fluid into the body of the user;

an infusion device communication system contained in the infusion device housing for receiving the communication including the data indicative of the determined concentration of the analyte in the user from the determining device communication system;

an infusion device processor contained in the infusion device housing and coupled to the infusion device communication system

for processing the data indicative of the determined concentration of the analyte in the user and controlling the infusion device;

a bolus estimator used in conjunction with the infusion device processor for calculating an estimated amount of fluid to be infused into the body of the user based upon the received data indicative of the determined concentration of the analyte in the user and a target concentration of the analyte in the user; and

an infusion device indicator to indicate when the estimated amount of fluid to be infused has been calculated;

wherein the *infusion device processor determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time*, and the *bolus estimator calculates the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is recent enough*.

The Campbell reference is generally directed to a medication infusion device that includes a menu structure that is used to control the infusion device. As acknowledged in the Office Action (please see page 2, para. 3), independent claim 1, as amended, patently improves upon the Campbell reference by reciting an *infusion device processor* that *determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time*, and the *bolus estimator calculates the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is recent enough.*

The Galley reference does not disclose or teach the infusion system of independent claim 1, as amended. The Galley reference is generally directed to an automated system for determining the timing and amount of insulin administration to a subject in the treatment of diabetes. Unlike independent claim 1, as amended, the Galley reference does not make any mention of an *infusion device processor* that *determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of*

the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time, and the *bolus estimator calculates the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is recent enough.* The Galley reference only shows that a feedback algorithm may be used in connection with basal rate control, and a feedforward algorithm may be used in connection with compensation control for meals and/or exercise (please see col. 6, lines 57-66). The Galley reference is entirely silent as to making a determination as to the age of the data to be used in calculating a fluid dosage (e.g., insulin dosage), and preventing such calculation if it is determined that the age of the data to be used in the calculation is too old and has expired, as claimed in independent claim 1, as amended.

In fact, the Galley reference actually teaches away from the infusion system of independent claim 1, as amended, in that if a current/recent glucose level value is unavailable, the Galley reference will actually make a prediction as to the current glucose level value and determine an insulin dosage recommendation based on this prediction (please see col. 5, lines 54-65). In contrast, the infusion system of independent claim 1, as amended, will prevent the calculation of a dosage if the age of the data used to calculate the dosage is too old, because predictions do not always accurately reflect the actual true value, and the concentration of analyte in the body can vary significantly over time for many patients. An improper dosage determined using inaccurately predicted data actually may cause greater harm. The infusion system of independent claim 1, as amended, which *prevents the bolus estimator from calculating*

the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time, and *calculates the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is recent enough*, is capable of providing safer and more accurate therapy based on recent data than using predictions of old and expired data that may potentially lead to harmful consequences. Accordingly, applicants respectfully submit that independent claim 1, as amended, distinguishes over the Galley reference.

The Jones references does not disclose or teach the infusion system of independent claim 1, as amended. The Jones reference is generally directed to an inexpensive blood glucose meter that reminds the user to recheck his or her blood glucose after a programmable interval when the meter detects a hypoglycemic event. Unlike independent claim 1, as amended, the Jones reference does not show an *infusion device processor* that *determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time,* and the *bolus estimator calculates the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is*

recent enough. The Jones reference merely teaches that a count-down timer is utilized in a blood glucose meter in connection with an alarm after some time has passed from the occurrence of a hypoglycemic event to alert the diabetic user to check his/her blood glucose level for a rebound or overtreatment hyperglycemic event (the Jones reference, para. 15).

Nowhere in the Jones reference is it contemplated that an *infusion device processor determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time,* and the *bolus estimator calculates the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is recent enough*, as recited in independent claim 1, as amended. The infusion device of independent claim 1, as amended, greatly differs from the Jones reference in that if it determines that the age of the blood glucose reading is too old, the bolus estimator in the infusion device is prevented from using the expired blood glucose reading, but otherwise the blood glucose reading may be utilized by the bolus estimator in the infusion device to calculate the estimated amount of fluid to be infused if the blood glucose reading is recent enough.

The Jones reference only shows a blood glucose meter having a simple count-down timer that alerts the user with an alarm at the end of the count-down time period from a hypoglycemic event to obtain a blood glucose reading to check for a rebound or overtreatment hyperglycemic event. The Jones reference is completely silent with respect to *determining an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined, preventing the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time,* and having the *bolus estimator calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is recent enough*, as recited in independent claim 1, as amended. In other words, the Jones reference fails to disclose or teach an infusion device that determines an age of a blood glucose reading, prevents the use of this blood glucose reading for calculating a bolus if the age of the blood glucose reading is too old, and calculating a bolus using the blood glucose reading if the blood glucose reading is recent enough, as claimed by the infusion system of independent claim 1, as amended. Accordingly, applicants respectfully submit that the Jones reference does not make up for the deficiencies of, and that independent claim 1, as amended, distinguishes over, the above-cited references.

The Estes reference is generally directed to methods and systems for the infusion of insulin. As acknowledged in the Office Action (please see page 4, para. 8),

independent claim 1, as amended, patently improves upon the Estes reference by reciting an *infusion device processor* that *determines an age of the data indicative of the determined concentration of the analyte in the user based on an amount of time that has elapsed since the concentration of the analyte in the user was determined*, and *prevents the bolus estimator from calculating the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user has expired due to the age of the data exceeding a predetermined amount of time,* and the *bolus estimator calculates the estimated amount of fluid to be infused based upon the determined concentration of the analyte if the data indicative of the determined concentration of the analyte in the user is recent enough*. Accordingly, applicants respectfully submit that independent claim 1, as amended, distinguishes over the above-cited references.

Claims 2-6, 10-34, and 95 all depend, directly or indirectly, from independent claim 1, as amended. Accordingly, applicants respectfully submit that claims 2-6, 10-34, and 95 distinguish over the above-cited references for the reasons set forth above with respect to independent claim 1, as amended.

In the May 13, 2009 Office Action, the Examiner rejected claims 1-6, 10-34, and 95 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 7,278,983. A Terminal Disclaimer is being filed concurrently herewith to overcome this rejection. Therefore, it is respectfully submitted that the double patenting rejection be withdrawn.

Applicants believe that the foregoing amendments place the application in condition for allowance, and a favorable action is respectfully requested. If for any

reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (818) 576-5291 to discuss the steps necessary for placing the application in condition for allowance should the Examiner believe that such a telephone conference would advance prosecution of the application.

Respectfully submitted,

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